REMARKS

Claims 36 to 65 are pending. No claims are added or canceled. Claims 40, 47, 55 and 62 have been amended to specify that the amino acid, amino acid derivative, or mixture is present in an amount ranging from about 0.0001% to about 20% by weight based on the weight of the formulation.

Rejections Under 35 U.S.C. § 112, ¶ 1

In the Office Action dated May 26, 2005, claims 40, 47, 55 and 62 were rejected under 35 U.S.C. § 112, first paragraph, because the range of 0.00002-20% by weight was said not to be supported in the specification. The claims in question, as noted above, have been amended to recite that the amino acid, amino acid derivative, or mixture is present in an amount ranging from about 0.0001% to about 20% by weight based on the weight of the formulation. Support for this range may be found, for example, in the specification at page 10, line 29 to page 11, line 19. This passage teaches that the total weight of particulate material (including dissolved and undissolved material) is suitably "20 to 0.001 wt% with respect to the total weight of the composition" and that the weight ratio of the first particulate material (in the instant claims, the medicament) to the second particulate material (in the instant claims, the suspension-enhancing material) "lies in the range of 1 : 0.1 to 1 : 500." If, for example, the total weight of particulate material (including dissolved and undissolved material) is taken as 20% by weight, and the ratio of medicament : suspension-enhancing material is taken to be 1 : 500, the weight percentage of suspension-enhancing material is 19.96% by weight or "about 20%," as recited in the claim. At the other end of the range, if the total weight of particulate material (including dissolved and undissolved material) is taken as 0.001% by weight, and the ratio of medicament : suspension-enhancing material is taken to be 1 : 0.1, the weight percentage of suspension-enhancing material is 0.0001% by weight. Thus, Applicants respectfully submit that the claimed range of from about 0.0001% to about 20% by weight is supported in the application. Accordingly, Applicants respectfully request that the rejection of claims 40, 47, 55 and 62 under 35 U.S.C. § 112, first paragraph, be withdrawn.

In the Office Action dated May 26, 2005, claims 37, 48, 52 and 63 were rejected under 35 U.S.C. § 112, first paragraph, because the medicaments cromolyn, epinephrine and ephedrine were alleged not to have support in the specification. Applicants respectfully traverse this rejection. Attention is directed in this regard to the paragraph bridging pages 14 and 15 of the specification. This paragraph provides a list of appropriate medicaments, which includes cromoglycate (line 23), adrenaline and ephedrine (both on line 27). Applicants respectfully submit that one of ordinary skill in the art would readily appreciate that "cromoglycate" is another name for cromolyn, and "adrenaline" is another name for epinephrine. Thus, Applicants respectfully submit that the specification provides support for the three medicaments in question, and request that the rejection of claims 37, 48, 52 and 63 under 35 U.S.C. § 112, first paragraph, also be withdrawn.

Rejections Under 35 U.S.C. § 102

Claims 36-65 stand rejected as allegedly being anticipated by Duan, et al., U.S. Patent No. 5,725,841 ("Duan"). Claims 36-37, 39-48, 50-52, 55-63, and 65 also stand rejected as allegedly being anticipated by Clark, et al., U.S. Patent No. 6,655,379 ("Clark"). The currently pending claims are not anticipated by either Duan or Clark, however, because neither reference discloses a medicinal aerosol formulation consisting essentially of a particulate medicament, a propellant, and a suspension-enhancing material selected from an amino acid, amino acid derivative, or mixture thereof, as described herein.

Duan (U.S. Pat. No. 5,725,841)

Duan describes a medicinal aerosol formulation containing a particulate drug and a dispersing aid "derived from" a hydroxyacid, a mercapto acid, or an amino acid. By "derived from," Duan means that the hydroxyacid, mercapto acid or amino acid must be in the form of linear, branched or cyclic *chains*, comprising between 3 and about 40 monomer units. (Duan at column 2, lines 44 to 60 and column 4, line 33.) Thus, Duan does not teach the use of amino acids and amino acid derivatives (as that term is used herein) *per se*, but only the use of *polypeptides*, *i.e.*, amino acid chains. Applicants note that the claims of U.S. 6,136,294 C1, from which the instant claims were copied, were found to be patentable over Duan, presumably for this reason.

It is clear that Duan does not disclose, or even contemplate, the use of a suspension-enhancing material selected from an amino acid, amino acid derivative (as the term would be understood by one of ordinary skill in the art) or a mixture thereof, as recited in the instant claims. Because Duan does not disclose every element of the pending claims, Duan does not anticipate the claimed subject matter. Accordingly, Applicants respectfully request withdrawal of the rejection of claims 36-65 under §102(b).

Clark (U.S. Pat. No. 6,655,379)

Clark describes methods and devices for delivering an active agent formulation to the lungs of a human patient at an inspiratory flow rate of less than 17 liters per minute, but does not disclose the use of a second material to enhance suspension in a medicinal aerosol formulation.

While Clark does briefly discuss the use of a second particulate material to improve dispersability (see Clark at column 6, lines 37-65), that segment of Clark's disclosure is only in the context of dry powder active agent formulations, rather than aerosolized particles in admixture with a propellant, which is the subject of the instant claims. Thus, the claimed use of a second material to enhance suspension quality in a propellant-containing aerosol formulation is not disclosed or suggested in Clark.

Because Clark does not disclose or suggest the use of a suspension-enhancing material in conjunction with a particulate medicament and a propellant in an aerosol system, as defined by the pending claims, Clark does not anticipate the claimed subject matter. Accordingly, Applicants respectfully request withdrawal of the rejection of claims 36-37, 39-48, 50-52, 55-63, and 65 under §102(e).

Conclusion

The foregoing represents a bona fide attempt to respond to all of the pending rejections and thereby to define allowable subject matter.

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